SECTION 5: 510(k) Summary

FEB 17 2012

Submitter

Mayborn Group Limited
Northumberland Business Park (West)
Dudley Lane
Cramlington
Northumberland
United Kingdom NE23 7RH
Tel: +44 191 250 1864
Fax: +44 191 250 1727
Owner/Operator Number: Establishment Registration No.: 3008729914

Contact Person

Neil Hewitt
Global Quality Manager,
Mayborn Baby & Child Division
Northumberland Business Park (West)
Dudley Lane
Cramlington
Northumberland
United Kingdom NE23 7RH
Phone Number + 44 191 250 1864
Fax Number: +44 191 250 1727
E-mail Address nhewitt@jackel.co.uk

Date Prepared

29th October 2011

Device Information

Trade name:	Closer to Nature
Common name:	Double Electric Breast Pump
Classification Name:	Pump, breast, powered
Review Panel:	Obstetrics / Gynecology
Product Code:	HGX
Device Class:	2

Indication for Use

Tommee Tippee Closer to Nature Double Electric Breast Pump is used to express and collect milk from the breast of a lactating woman.

Device Description

This Double Electric Breast Pump product is designed to provide everything a mother will need to start expressing, storing and feeding. The pump unit has 5 alternate settings of suction level during expression. The collect and protect breast milk storage system enables the user to express directly into the small graduated 2oz or 4oz pod, which fits into "Closer to Nature" bottles for feeding. The product is designed to use, one pod size per 5oz bottle and 2 pod sizes for a 9oz bottle for expressing, storing and feeding. This device is mains or battery powered.

Included with the double electric breast pump motor unit and vacuum system are:

1 off - Carry Bag to hold pump and accessories

2 off - Feeding bottles 5oz with teats - as per Mayborn Single Electric Breast Pump – K110343

2 off - Feeding bottles 9oz without teats

4 off - Milk storage lids - as per Mayborn Single Electric Breast Pump – K110343

2 off - 4oz Milk storage pods

4 off - 2oz Milk storage pods as per Mayborn Single Electric Breast Pump – K110343

1 off - Milk storage pod tray

1 off - Bottle bag for feeding bottles with milk storage lid

6 off - Disposable Breast pads - as per Mayborn Single Electric Breast Pump – K110343

2 off – Spare valves

2 off – Spare Diaphragms

2 off – Hygiene cover – as per Mayborn Single Electric Breast Pump - K110343

Devices to which substantial equivalence is claimed:

510(k) number	Trade or propriety name
K973501	Ameda Purely Yours Ultra

Device Comparison to Legally Marketed Device

Following is a comparison chart outlining differences and similarities between the Tommee Tippee Closer to Nature Double Electric Breast Pump, and the Ameda Purely Yours Ultra.

	New Product	Predicate
Device Name	Tommee Tippee Closer to Nature Double Electric Breast Pump	Purely Yours Ultra
Manufacturer	Mayborn Group Limited	Ameda / Evenflo
510(k) number	To be assigned	K973501
Product Code	HGX	HGX
Classification	2	2
Intended use	As described in 21 CFR 884.5160	As described in 21 CFR 884.5160
Power Source	9 V DC Rechargeable 7.4V lithium polymer battery or electric adaptor	9V DC 6 *1.2 V rechargeable batteries or electric adaptor
Pump type	Reciprocating Diaphragm	Reciprocating Piston
Single or Double Pumping	Single + Double	Single + double
Suction Levels	Yes – 1 Pre set on starting and 4 User Selectable Separate Speed Rates	Variable
Highest Vacuum Setting - double pump	360mbar	230mbar
Lowest Vacuum Setting - double	130mbar	110mbar
Highest Vacuum Setting - single pump	450mbar	330mbar
Lowest Vacuum Setting - single pump	200mbar	190mbar
Adjustable Cycle Speed	No	Yes - Variable
Range of Cycle Speeds	Fixed	30-60 cycles per minute
Overflow Protection	Yes	Yes
Breast Cup-to-Breast Interface DEV- 1063-4	Soft Silicone Wacker R401 and Toshiba TSE 260	Hard PP

Both the *Ameda Purely Yours Ultra* and the Closer to Nature Double Electric Breast Pump are identified by the FDA as Product code HGX under CFR section 884.5160.

Both Units use a rechargeable batteries or mains adaptor.

Both units use a single diaphragm / piston pump.

The Horn (DEV 1063-4) is used on the Closer to Nature Single Breast Pump K110343 and has been utilised on the Closer to Nature Double Electric Pump and is the approved with respect to biocompatibility.

Key Areas

Mayborn Baby and Child during the development of the product identified four key comparative areas which would ensure the safety and integrity of the Closure to Nature Double Electric Breast Pump would match or exceed the ability of the *Ameda Purely Yours Ultra*.

These cover the following:

1. Pump vacuum when installed in the housing - mbar
2. Suction flow rate – millilitres per minute
3. Noise Level – decibel level
4. Materials

1. Pump vacuum when installed in the housing

The first key comparative area identified was the vacuum capability of the pumps when installed in the housing. A direct comparison of the pumps was carried out as below.

Vacuum While Double Pumping

Device Name	**Tommee Tippee Closer to Nature**	**Purely Yours Ultra**
Setting 1	**160mbar**	**120mbar**
Setting 2	**210mbar**	**Not tested – as variable**
Setting 3	**260mbar**	**180mbar**
Setting 4	**300mbar**	**Not tested – as variable**
Setting 5	**330mbar**	**220mbar**
Setting 6		
Setting 7		
Setting 8		
Setting 9		

Vacuum While Single Pumping

Device Name	Tommee Tippee Closer to Nature	Purely Yours Ultra
Setting 1	240mbar	200mbar
Setting 2	320mbar	Not tested – as variable
Setting 3	380mbar	280mbars
Setting 4	420mbar	Not tested – as variable
Setting 5	450mbar	330mbar
Setting 6		
Setting 7		
Setting 8		
Setting 9		

This shows there is no significant difference in the devices.

2. Suction flow rate

The second key comparative area identified was the suction rate of the pump in terms of its ability to flow liquid. The comparison of the pumps identified the following:

Single Pump

Device Name	Tommee Tippee Closer to Nature	Purely Yours Ultra
Setting 1	80ml	108ml
Setting 2	Not tested	Not tested
Setting 3	115ml	147ml
Setting 4	Not tested	Not tested
Setting 5	145ml	160ml
Setting 6		

Double Pump

Device Name	Tommee Tippee Closer to Nature	Purely Yours Ultra
Setting 1	LH 73ml RH 65ml	LH 75ml RH 80ml
Setting 2		
Setting 3	LH 105ml RH 95ml	LH 88ml RH 103ml

Setting 4	[redacted]	[redacted]
Setting 5	LH 135ml RH 125ml	LH 120ml RH 135ml
Setting 6	[redacted]	[redacted]

All tested on high suction with both pumps attached over duration of 2 minutes 30 seconds.
Reservoir water level was maintained at 3 litres.
CTN Fast Flow teats used in rig.
Double CTN was tested without the top of the pump attached.

This shows there is no significant difference in the devices.

3. Noise Level

The third key comparative area identified was the noise level of the pump in terms of being discreet. The comparison of the pumps identified the following based on the lowest, middle and highest settings.

Device Name	Tommee Tippee Closer to Nature	Purely Yours Ultra
Setting 1	64.3db	62.6db
Setting 2	[redacted]	[redacted]
Setting 3	63.4db	62.5db
Setting 4	[redacted]	[redacted]
Setting 5	63.7db	63db
Setting 6	[redacted]	[redacted]

This shows there is no significant difference in the devices.

4. Materials

The fourth key area identified was material selection; all the materials specified and tested for use in the Closer to Nature Double Electric Breast Pump have been selected to ensure they meet the appropriate FDA regulations concerning food contact and or biocompatibility to ensure maximum protection of the infant from contaminated food and maximum comfort for the mother.

All milk and human contact components are manufactured from materials that meet FDA food additive criteria as set forth in Part 21 Code of Federal Regulations Parts 176, 177 and 178.

The skin contacting materials associated with the Double Electric Breast Pump satisfy all required biocompatibility testing in accordance with ISO 10993 parts 5 and 10 for skin contact.

This shows there is no significant difference in the devices.

Conclusion

Tommee Tippee Closer to Nature Double Electric Breast Pump, subject of this submission, constitutes a safe, reliable and effective medical device, meeting all the declared requirements of its intended use. The device presents no adverse health effects or safety risks when used as intended.

Tommee Tippee Closer to Nature Double Electric Breast Pump has the same intended use and fundamental scientific technology as its predicate device – the *Ameda Purely Yours Ultra* Breast Pump (K973501).

Tommee Tippee Closer to Nature Double Electric Breast Pump was tested against its predicate, and was found to be substantially equivalent based on the summary information above and the detailed evaluation within this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mayborn Group Limited
% Ms. Paula Wilkerson
Medical Device Program Manager - Intertek 3rd Party Program
Intertek
2307 East Aurora Rd. Unit B7
TWINSBURG OH 44087

FEB 17 2012

Re: K113664
Trade/Device Name: Closer to Nature Double Electric Breast Pump
Regulation Number: 21 CFR§ 884.5160
Regulation Name: Powered breast pump
Regulatory Class: II
Product Code: HGX
Dated: January 31, 2012
Received: February 6, 2012

Dear Ms. Wilkerson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

MAYBORN
BABY AND CHILD

510K Submission

Product Closer to Nature – Double Electric Breast Pump

Project File Number – DEV 1092

SECTION 4: **Indications for Use**

510(k) Number: K113664

Device Name:

Closer to Nature Double Electric Breast Pump

Indications for Use:

Tommee Tippee® Closer to Nature® Double Electric Breast Pump is used to express and collect milk from the breast of a lactating woman.

Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ___√___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K113664